UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Robert M. Hansen
The Marbury Law Group
11800 Sunrise Valley Drive, 15th Floor
Reston, VA 20191-5302

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,368,274

MAILED
SEP 13 2012
OPLA

FINAL DECISION REGARDING INTERIM PATENT TERM EXTENSION APPLICATION UNDER 35 U.S.C. § 156(d)(5) FOR U.S. PATENT NO. 5,368,274

This is in response to the application for interim extension of the term of U.S. Patent No. 5,368,274 ("the '274 patent") filed under 35 U.S.C. § 156(d)(5) in the United States Patent and Trademark Office ("USPTO") on August 31, 2012 ("the PTE Application"). Flowonix Medical, Inc. ("Applicant"), assignee and owner of the '274 patent, filed the PTE Application. Applicant seeks extension based upon the "continuing" regulatory review of the premarket approval application (PMA) No. P080012 for the Prometra Programmable Pump System ("the Medical Device") under Section 515 of the Federal Food Drug and Cosmetic Act ("FFDCA"). Because the USPTO has determined, and the FDA has confirmed, that PMA No. P080012 for the Medical Device was approved on February 7, 2012 and the approval has not been withdrawn, the regulatory review period for PMA No. P080012 is completed and interim extension pursuant to 35 U.S.C. 156(d)(5) is not available. Thus, the PTE Application is **DENIED**.

A. Factual Background

1. On November 29, 1994, the USPTO granted the '274 patent to Theodore J. Falk et al., who assigned their rights to Wilson Greatbatch Limited, a predecessor to Flowonix Medical Inc.

2. On February 7, 2012, the FDA approved PMA No. P080012 for the Prometra Programmable Infusion Pump System indicated for use for intrathecal infusion of Infomorph (preservative-free morphine sulfate sterile solution) or preservative-free saline 0.9% saline solution.

3. On August 31, 2012, Applicant filed a request for interim extension pursuant to the provisions of 35 U.S.C. 156(d)(5) seeking extension of the '274 patent due to continuing regulatory review of the Medical Device.

4. On September 12, 2012, USPTO requested information from FDA regarding whether the approval of February 7, 2012 for the Medical Device had been withdrawn. FDA confirmed that the February 7, 2012 was a grant of permission to commercially market or use the Medical Device and that the approval has not been withdrawn (see attached email

correspondence).

5. The term of the '274 patent will expire on September 17, 2012.

B. Analysis

Applicant has filed for an interim extension under 35 U.S.C. § 156(d)(5). That provision provides for interim patent term extension where regulatory approval of a product claimed in a patent has been sought, but not yet received. Section 156(d)(5)(A) provides in relevant part:

> If the owner of record of the patent or its agent reasonably expects that the applicable regulatory review period described in paragraphs (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent **may extend beyond the expiration date** of the patent term in effect, the owner or its agent may submit an application to the Director for an interim extension during the period beginning 6 months, and ending 15 days before such term is due to expire.

35 U.S.C. § 156(d)(5)(A) (emphasis added). By its express terms, section 156(d)(5)(A) requires that a regulatory review period described in paragraphs (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) must have begun and may extend beyond the expiration date of the patent. Paragraph (3)(B)(ii) of subsection (g) applies to medical device products and identifies the regulatory review period to begin when "an application was initially submitted with respect to the device under section 515" and for the regulatory review period to end, "on the date such application was approved under such Act. . . ." Paragraph (3)(B)(ii) is commonly considered to refer to the "approval phase" for a medical device. Thus, under section 156(d)(5)(A), the owner of record of the patent or its agent must show that the approval phase for the Medical Device has commenced and may extend beyond the expiration date of the patent term in effect.

Here, Applicant's regulatory review period set forth in section 156(g)(3)(B)(ii) has been completed and the PMA for the Medical Device has been approved. Applicant admits as much in its interim extension application, stating, "[w]hile the FDA did send a letter approving Applicant's PMA on February 7, 2012, the FDA has not, to date, given applicant final permission to use or market the Medical Device commercially. See Exhibit F for a more thorough explanation." Application at 2.

Applicant asserts that an interim extension is appropriate because the original manufacturer of component parts of the Medical Device ceased manufacturing the components and FDA must find that the new manufacturer of the components of the Medical Device is acceptable. Based on this new manufacturer clearance, Applicant asserts that the regulatory review period is continuing. Application at Exhibit F. On the contrary, the language of 35 U.S.C.

156(g)(3)(B)(ii) indicates that the regulatory review period ends, "on the date such application was approved un such Act." Whether Applicant can commercially produce the product is irrelevant to determining the end of the regulatory review period. The only relevant event for determining conclusion of the regulatory review period is the date a PMA was approved. Here, that date is February 7, 2012. Furthermore, although a manufacturing change in a facility which produces component parts for a medical device may require submission of a PMA supplement pursuant to 21 C.F.R. 814.39(a)(3), such additional submissions to FDA do not negate or act to withdraw or withhold the original approval of the PMA for the Medical Device. Submission of a supplement to a PMA does not act to rescind or withdraw the approval of a PMA. Here, no such evidence exists that the approval of PMA No. P080012 for the Medical Device that FDA issued on February 7, 2012 has been withdrawn, rescinded or is otherwise withheld. On the contrary, on June 14, 2012, FDA published a listing (77 Fed. Reg. 35690) of approved PMAs including the availability of safety and effectiveness summaries for the approved PMAs. The Prometra Programmable Pump Infusion System was included in this listing. The notice specifically states, "[t]he following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2012, through March 31, 2012." Thus, because PMA No. P080012 for the Medical Device was approved on February 7, 2012, which is prior to the expiration date of the '274 patent, the requirement that the regulatory review period in set forth in 156(g)(3)(B)(ii) for a premarket approval application of a medical device may extend beyond the expiration date of the patent cannot be met in order for the USPTO to grant an interim extension under 35 U.S.C. 156(d)(5). Accordingly, the application for interim patent term extension is **denied**.

Inquiries regarding this communication should be directed to Mary C. Till at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Brian E. Hanlon

Brian E. Hanlon
Director
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

Till, Mary

From: Stevens, Alan M <Alan.Stevens@fda.hhs.gov>
Sent: Wednesday, September 12, 2012 10:16 AM
To: Amatrudo, Vincent
Cc: Till, Mary; Purohit-Sheth, Tejashri; Chapman, Richard; Watson, Anthony
Subject: RE: PTE application for U.S. Patent No. 5,368,274 based on FDA review of Prometra (PMA No. 080012)

Vincent,

P080012 is an approved PMA as of February 7, 2012 and the approval has not been withdrawn.

Supplements are required for modifications that impact safety or effectiveness, as described in 21 CFR 814.

LCDR Alan Stevens
Infusion Pump Team Leader
General Hospital Devices Branch
Office of Device Evaluation
Center for Devices and Radiological Health
U.S. Food and Drug Administration
P: 301-796-6294
F: 301-847-8109

From: Amatrudo, Vincent
Sent: Wednesday, September 12, 2012 9:31 AM
To: Stevens, Alan M
Cc: Till, Mary
Subject: FW: PTE application for U.S. Patent No. 5,368,274 based on FDA review of Prometra (PMA No. 080012)

Hi Alan, I understand you are knowledgeable about this PMA. Could you please confirm that it has been approved and has not been withdrawn? I do not think we can share whether there is a pending supplement with PTO, so please do not provide this information. It seems sufficient to say that a supplement would be required for a change of manufacturer under 21 CFR 814.39(a)(3) if it affects safety/effectiveness; please confirm this is your understanding. Thanks.

From: Till, Mary [mailto:Mary.Till@USPTO.GOV]
Sent: Wednesday, September 12, 2012 8:58 AM
To: Amatrudo, Vincent
Subject: PTE application for U.S. Patent No. 5,368,274 based on FDA review of Prometra (PMA No. 080012)

Dear Vince:

Further to my voicemail of September 11, 2012, on August 31, 2012, the patent owner of the above referenced patent filed an interim extension pursuant to the provisions of 35 U.S.C. 156(d)(5). Such an interim extension is available when a product, requiring premarket approval by FDA and currently undergoing active review by the FDA before its first permitted commercial marketing, will not be approved before a patent which covers the product will expire. Here, the patent owner is seeking extension of the patent based on what the patent owner characterizes as "continuing" regulatory review. We note, however, that FDA approved the PMA for the Prometra product in its letter of February 7, 2012. Can you please confirm that the PMA P080012 has received permission for commercial marketing or use of the Protmetra product and that the approval has not been rescinded, withdrawn, withheld or in any other way is not effective, which would mean that the above captioned PMA is not approved and is continuing its regulatory review period?

Sincerely,
Mary

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
United States Patent and Trademark Office

600 Dulany St.
Alexandria, VA 22313

(571) 272-7755